

Message

From: Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]
Sent: 3/16/2020 3:35:01 PM
To: Doherty, Michael [Doherty.Michael@epa.gov]
CC: Niman, Aaron [niman.aaron@epa.gov]
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

It seems to me that Option (2) would certainly go against the spirit of Bayer deciding that it did not want to release the data. EPA would, in effect, be doing an end run around Bayer's (data owner) request that the data to support AgLogic's request not be released.

David.

From: Doherty, Michael
Sent: Monday, March 16, 2020 11:14 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Niman, Aaron <niman.aaron@epa.gov>
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

I wonder, also, if it's worth reaching out to Soren Madsen and Ian Dewhurst (current WHO JMPR Chair) to appraise them of the situation and to see what their take is on Dr. Hodges' Option 2. My guess is that it is not a viable option.

From: Miller, David <Miller.DavidJ@epa.gov>
Sent: Monday, March 16, 2020 11:10 AM
To: Doherty, Michael <Doherty.Michael@epa.gov>
Cc: Niman, Aaron <niman.aaron@epa.gov>
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

My response will probably be that he needs to do what he was instructed to do late last year: submit a FOIA request so we can either say yah or nay. Without a formal official request in hand, EPA cannot make a formal official decision.

I relayed that sentiment to a bunch of folks in an email last year. I will likely send that out again to remind folks... and let them know that we are in the exact same position we were 6 months ago.

Larry says "I suggest that the aldicarb periodic review be rescheduled from 2021 until 2022 to provide additional time to get the studies released." It's not clear to me that Aaron and I want to make that recommendation to Karina as it would seem to suggest Aaron and I think there is a viable path forward in getting that data released without a formal FOIA request from AgLogic. Nor would want for Karina to grant the extension in ignorance of the real situation or have her and Codex think it is just EPA being a typically slow government bureaucracy that is not able to get its act together for what will be now for almost two years.

David.

From: Doherty, Michael
Sent: Monday, March 16, 2020 11:00 AM

To: Miller, David <Miller.DavidJ@epa.gov>

Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Yup – you nailed it.

□

From: Miller, David <Miller.DavidJ@epa.gov>

Sent: Monday, March 16, 2020 10:41 AM

To: Doherty, Michael <Doherty.Michael@epa.gov>

Subject: FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

What'd I tell ya ... ?

David.

From: Larry Hodges [<mailto:larryhodges@meycorp.com>]

Sent: Monday, March 16, 2020 10:18 AM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>

Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear David,

Do you have any suggestions regarding the aldicarb data review by the JMPR? All of the necessary studies have been submitted to the EPA by Bayer CropScience but we (AgLogic Chemical) have no authority to release them to the JMPR and Bayer will not provide the studies or give permission to the EPA to release the studies to the JMPR. Furthermore, it appears that the JMPR will not request the studies from EPA through the FOIA.

I can only see two alternatives. (1) the EPA could provide the studies directly to the JMPR for review or (2) the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR.

If neither of these alternatives is feasible I suggest that the aldicarb periodic review be reschedule from 2021 until 2022 to provide additional time to get the studies released.

Thanks for the help,

Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Budd, Karina <Karina.Budd@awe.gov.au>

Sent: Thursday, March 12, 2020 6:14 PM

To: Larry Hodges <larryhodges@meycorp.com>

Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron

<niman.aaron@epa.gov>; doherty.michael@epa.gov; IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow.Calvin@epa.gov; Johnson.Marion@epa.gov; Antoine Puech <antoinepuech@meycorp.com>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; MADSEN, Soren <madsens@who.int>

Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Larry,

Thankyou for this commodity information and for explaining the status of your aldicarb nomination. I understand the difficult situation around this nomination.

As Chair of the Priorities EWG, I am guided by the Risk Analysis Principles of the Codex Procedural Manual.

Unfortunately I am not able to assist you in the freedom of information application.

This is a matter for your company, Bayer and US EPA to resolve, with the assistance of JMPR which will provide guidance on acceptance of the requisite data package.

Please continue to work with the US EPA.

Kind regards,

Karina Budd

Director | Residue Chemistry & Laboratory Performance Evaluation, National Residue Survey | +61 2 6272 5795 | +61 408 695 904

Karina.Budd@awe.gov.au

Department of Agriculture, Water and the Environment
Residues & Food Branch | Exports Division
18 Marcus Clarke Street, Canberra ACT 2601 Australia
GPO Box 858, Canberra ACT 2601 Australia

From: Larry Hodges [<mailto:larryhodges@meycorp.com>]

Sent: Thursday, 12 March 2020 3:19 AM

To: Budd, Karina <Karina.Budd@agriculture.gov.au>

Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron

<niman.aaron@epa.gov>; doherty.michael@epa.gov; IMCEAMAILTO-

Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow.Calvin@epa.gov; Johnson.Marion@epa.gov;

Antoine Puech <antoinepuech@meycorp.com>

Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Karina,

Thanks for helping me join the CCPR-Priorities-2019 electronic working group (EWG). I reviewed the listing for the 2021 Periodic Review and see that aldicarb (117) is tentatively scheduled for review in 2021. A note in the comments section requested advice on the commodities.

The commodities are: Citrus (oranges, grapefruit, lemons, limes), Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, Sweet Potatoes. I have also listed these on the attached 2021 Periodic Review Excel document.

We are still trying to arrange for submission of the supporting toxicology and residue studies to the JMPR. However, as explained in previous emails, AgLogic Chemical LLC is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US Environmental Protection Agency (EPA) by aldicarb's previous registrant, Bayer CropScience. AgLogic is not allowed to have copies of the actual studies that support registration and, therefore, despite our best intentions, we are not able to submit these studies to the JMPR for review.

Although Bayer will not consent to the EPA's direct release of aldicarb toxicology and residue studies to the JMPR, the EPA may be able to provide the studies directly to the CCPR without agreement from Bayer if done so through a Freedom of Information Request (FOIA).

I suggest that we proceed with FOIA requests for the toxicology and residue studies or, alternatively, since the EPA already has the supporting studies, the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR.

Your help with an appropriate way forward will be most appreciated.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Budd, Karina <Karina.Budd@agriculture.gov.au>
Sent: Monday, November 4, 2019 4:08 PM
To: Larry Hodges <larryhodges@meycorp.com>
Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; doherty.michael@epa.gov; IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow.Calvin@epa.gov; Johnson.Marion@epa.gov; Antoine Puech <antoinepuech@meycorp.com>
Subject: FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Larry,

Ian Reichstein is on extended leave and I am managing the CCPR Priorities working group. Regarding this schedule, aldicarb has been moved from the 2020 periodic review to the 2021 periodic review (see attached).

Aldicarb was not included in the recent JMPR data call in for JMPR review in 2020:
http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/2020_Call_for_data_Final.pdf

I encourage you to join the CCPR-Priorities-2019 electronic working group (EWG), where updated priority and schedule documents will be loaded.

The EWG platform link is at: <http://forum.codex-alimentarius.net/index.php>

You will need to register for the online platform: <http://forum.codex-alimentarius.net/viewtopic.php?f=13&t=110>

The Priorities EWG is titled "*Establishment of CCPR schedules and priority list for the evaluation of pesticides by JMPR*".

The online invitation to this forum is at

http://www.fao.org/fileadmin/user_upload/codexalimentarius/invitations/Australia-CCPR-EWG%20PL%20invitation%202019.pdf

If you have any problems with this process, there are videos

(<https://www.youtube.com/watch?v=EJn9k7wNSwk&feature=youtu.be>) and your national Codex contact point should be able to provide assistance.

Thankyou for following up with us, and I look forward to further updates closer to the next meeting of CCPR.

Kind regards,

Karina Budd

Karina Budd

Director - Residue Chemistry and Laboratory Performance Evaluation Section

National Residue Survey | Exports Division | Department of Agriculture

Phone +61 2 6272 5795 | Mobile +61 408 695 904 |

Email karina.budd@agriculture.gov.au

18 Marcus Clarke Street, Canberra ACT 2601 Australia

GPO Box 858, Canberra ACT 2601 Australia

----- IMPORTANT - This email and any attachments have been issued by the Australian Government Department of Agriculture, Water and the Environment. The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Department. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Department of Agriculture, Water and the Environment is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----